Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx..01

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

June 17, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx..01.

COMMON NAME:

Medical device data converter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
MSX	System, Network And Communication, Physiological Monitors	870.2300

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The S/5™ Device Interfacing Solution, N-DISxxxx..01 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) S/5™ Device Interfacing Solution, N-DISxxxx..00 (K012531).

DEVICE DESCRIPTION as required by 807.92(a)(4)

External devices are connected to the monitoring system by using small plug-in converter modules that handle the communication between the device and S/5 monitoring system. These DIS converter modules convert the data coming from the connected device to a format that can be utilized in the Datex-Ohmeda S/5 Anesthesia Monitor, Datex-Ohmeda S/5 Critical Care Monitor, Datex-Ohmeda S/5 Compact Anesthesia Monitor, Datex-Ohmeda S/5 Compact Critical Care Monitor, or Datex-Ohmeda S/5 FM. The use of a DIS system consists of making the physical connections connecting external devices to DIS and linking DIS modules together to make a complete bus. Then the DIS transfers data between a device and the S/5 monitoring system. The user can then select the source of measurement data for physiologic parameters displayed on the Datex-Ohmeda monitor. The first DIS converter module is connected to the socket at the Datex-Ohmeda S/5 monitor. In S/5 Anesthesia Monitor, and S/5 Critical Care Monitor the DIS socket is located at the rear of the monitor and in S/5 Compact Anesthesia Monitor, S/5 Compact Critical Care Monitor, and S/5 FM monitor it is located in left hand side of the monitor. Additional DIS converter modules in a system are connected to each other with the bus cable. The external device is connected to the DIS converter module with a device specific cable. Up to ten DIS converter modules can be connected in the system. The maximum number of simultaneous interfaces is ten. The maximum length of interface cable is 10 meters (33ft). The number of DIS interfaces that can be used depend on the length of the interface cables and the particular monitor used. The Device Interfacing Solution supports interfacing of the following device categories: ventilators/anesthesia machines, stand-alone monitors, blood gas analyzers and heart-lung machines. The Device Interfacing Solution can interface numerical, waveform and event type of data from the external device. Alarms are not transferred. Interfaced data can be displayed on the monitor screen, trended, printed and used for record keeping purposes. Also, interfaced physiologic data is sent to the network to be viewed at the Central station monitor.

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The Datex-Ohmeda S/5 Device Interfacing Solution, DIS, is intended to be used with a Datex-Ohmeda monitoring systems for transferring data between external devices and a monitor.

Indications for use:
The Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx..01, is indicated for data transfer between stand-alone monitors, ventilators/anesthesia machines, blood gas analyzers, and heart-lung machines and Datex-Ohmeda bedside monitors for displaying and patient care information purposes. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The S/5™ Device Interfacing Solution, N-DISxxxx..01 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) S/5™ Device Interfacing Solution, N-DISxxxx..00 (K012531).
The S/5™ Device Interfacing Solution (later referred to as DIS) is an additional part of a Datex-Ohmeda modular S/5™ monitoring system. The Device Interfacing Solution enables connection of external medical bedside devices such as stand-alone monitors, ventilators/anesthesia machines, blood gas analyzers and heart-lung machines to the monitoring systems.
The S/5™ Device Interfacing Solution is a module that can be placed close to the interfaced external device. The module is device specific: a separate DIS module is needed to interface each external device. The DIS is able to transfer numerical, waveform and event type of data such as ventilator settings, laboratory results and heart-lung machine settings.
The N-DISxxxx..01 like the predicate N-DISxxxx..00 (K12531) does not perform any physiological measurements itself. It transfers data between connected external devices and S/5™ monitoring system. The Datex-Ohmeda S/5™ monitor displays, trends and uses data for calculations and transfers it to the record keeping system and network accordingly.
The N-DISxxxx..01, in terms of general function is identical to its S/5™ Device Interfacing Solution, N-DISxxxx..00 (K012531). The N-DISxxxx..01 simply extends capability of Interfacing Solution to the Datex-Ohmeda S/5™ monitor. Neither the Device Interfacing Solution, N-DISxxxx..01 nor the predicate N-DISxxxx..00 transfer alarms. A new feature of the N-DISVENT module is that it can transfer a current clock time from the monitor to the Datex-Ohmeda AiSys Carestation (only this ventilator). This synchronization is done to have same clock time both in the ventilator and monitor. The same clock time in both devices is important for the record keeping purposes. This clock time transfer (time synchronization) is done only when there is no case open in the the monitor/ventilator. The comparison above as well as supporting data and analysis shows that there are no new questions of safety and effectiveness for the S/5™ Device Interfacing Solution or accessories.

The N-DISxxxx..01 has following similarities compared to the predicate N-DISxxxx..00 (K012531).

- ·Identical intended use and nearly identical indications for use
- ·The same (improved) electronic board
- ·Essentially the same software.
- ·Uses same operating principle
- ·Have same user interface at the monitor
- ·Have the same safety and effectiveness
- ·Are manufactured using the same processes

The main differences between the new N-DISxxxx..01 and the predicate N-DISAxxxx..00 (K0124531) are as follows:

- ·Electronic board uses various voltage comparing the old board. With FM monitor DIS uses a 15Vdc power supply instead of old DIS modules which use 8Vdc. New board supports both voltages and automatically selects the correct voltage.
- ·A new N-DISVENT module can communicate also with other Datex-Ohmeda ventilators and it will replace the N-DISAEST module.
- ·N-DISVENT can transfer time from monitor to ventilator (only with Datex-Ohmeda AiSys Carestation). This is used for time synchronization.

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the S/5™ Device Interfacing Solution, N-DISxxxx..01 is substantially equivalent to the predicate S/5™ Device Interfacing Solution, N-DISxxxx..00 (K012531).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx..01. has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- EN 60601-1:1990 + Amdt 1:1993 + Amdt 2:1995 + Amdt 3:1996 Medical electrical equipment Part 1: General requirements for safety
- IEC 60601-1:1988 +Amdt 1:1991 + Amdt 2:1995
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 + Amdt 2:1998
- UL 2601-1,October 24, 1997
- IEC 60601-1-2:2001
- Electromagnetic compatibility - Requirements and tests
- EN 980: 1996 Terminology, symbols and information provided with medical devices- Graphical symbols for use in the labeling of medical devices
- EN 1041 1998 Terminology, symbols and information provided with medical devices; information supplied by the manufacturer with medical devices.
- Protection against ingress of liquid: EN 60529 (IPX1):1992

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the S/5™ Device Interfacing Solution, N-DISxxxx..01 and it is substantially equivalent in safety and effectiveness to the legally marketed (predicate) S/5™ Device Interfacing Solution, N-DISxxxx.00 (K012531).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

GE Healthcare
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K051634
Trade Name: Datex-Ohmeda S/5 Device Interfacing Solution N-DISxxxx..01
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Network and Communication System
Regulatory Class: Class II (two)
Product Code: MSX
Dated: June 17, 2005
Received: June 20, 2005

Dear Mr. Kent:

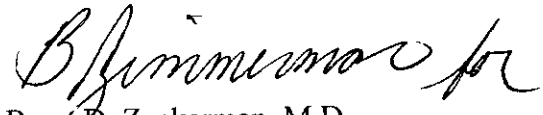
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051634

Device Name: Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx..01

Indications for Use:

The Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx..01, is indicated for data transfer between stand-alone monitors, ventilators/anesthesia machines, blood gas analyzers, and heart-lung machines and Datex-Ohmeda bedside monitors for displaying and patient care information purposes.

The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051634